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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,271	08/16/2001	Todd Dickinson	A-68950-2/RMS/DCF/SRN	2224

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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	8

DATE MAILED: 09/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

CTNF

Office Action Summary	Application No.	Applicant(s)	
	09/931,271	DICKINSON ET AL.	
	Examiner	Art Unit	
	B. J. Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election

1. Applicant's election without traverse of Group I, Claims 1-12 and 15-26 in Paper No. 7 is acknowledged. Claims 13 and 14 have been cancelled without disclaimer or prejudice.

Information Disclosure Statement

2. The references listed on the 1449 received 15 October 2001 have been reviewed and considered. Additionally, the cited Patent Applications which were available to the examiner have been reviewed.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) and 120 is acknowledged. However, the Provisional Application filed 10 February 2000 nor Application 09/782,588 filed 12 February 2001 upon which priority is claimed, does not provide adequate support under 35 U.S.C. 112 for claims 1-12 and 15-26 of this application. The instant claims are drawn to an array and method of making the array comprising a rigid support, a molded layer adhered to said rigid support and a layer of bonding agent adhering said rigid support to said molded layer. Neither the Provisional nor the '588 Application provide support for the "adhered" molded layer or the "layer of bonding agent adhering said rigid support" to the molded layer. Therefore, the effective filing date for the instant application is the actually filing date i.e. 16 August 2001.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 18 is indefinite in the recitation "(b) are carried out by a continuous process of rolling said cylindrical template structure" because it is unclear how rolling the template removes the moldable material from the template. It is suggested that Claim 18 be amended to clarify.

b. Claim 20 is indefinite for the recitation "said flexible molded layer is stored in rolled form." because it is unclear whether the layer is stored before or after steps (c) and/or (d) of Claim 1. It is suggested that Claim 20 be amended to clarify.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international

application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 1-3, 5-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Demers et al (U.S. Patent No. 5,840,256, issued 24 November 1998).

Regarding Claim 1, Demers et al disclose an array composition comprising a rigid support (Fig. 4, #300); a molded layer (Fig. 4, #320) with at least a first assay location comprising discrete sites wherein said molded layer is adhered to said rigid support; a layer of bonding agent adhering said rigid support to said molded layer (Column 7, lines 34-59 and Column 9, lines 4-64); and a population of microspheres comprising at least a first and a second subpopulation wherein said first population comprises a first bioactive agent and said second population comprises a second bioactive agent wherein said microspheres are randomly distributed on said sites (Column 7,lines 19-32).

Regarding Claim 2, Demers et al disclose the array wherein said sites are separated by a distance of at least about 5μ m (Column 3, lines 48-67).

Regarding Claim 3, Demers et al disclose the array wherein said sites are separated by a distance of at least about 100μ m (Column 3, lines 48-67).

Regarding Claim 5, Demers et al disclose the array wherein said molded layer comprises at least a second assay location (Fig.5).

Regarding Claim 6, Demers et al disclose the array wherein said assay locations are separated by a fluid barrier e.g. conduit (Column 7, lines 51-59) and/or gasket (Column 9, lines 4-10).

Regarding Claim 7, Demers et al disclose the array wherein said fluid barrier is a physical fluid barrier e.g. conduit (Column 7, lines 51-59) and/or gasket (Column 9, lines 4-10).

Regarding Claim 8, Demers et al disclose the array wherein said physical fluid barrier comprises a material that is added to said molded layer i.e. gasket (Column 9, lines 4-10).

Regarding Claim 9, Demers et al disclose the array wherein said molded layer comprises said physical fluid barrier i.e. gasket (Column 9, lines 4-10).

Regarding Claim 10, Demers et al disclose the array wherein said fluid barrier comprises a physico-chemical surface coating e.g. silicone gasket (Column 9, lines 4-64).

Regarding Claim 11, Demers et al disclose the array wherein the bioactive agents comprise nucleic acids (Column 8, lines 32-37).

Regarding Claim 12, Demers et al disclose the array wherein the bioactive agents comprise proteins (Column 8, lines 32-37).

8. Claims 1-3, 5-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Walt et al (U.S. Patent No. 6,327,410 B1, filed 11 September 1998).

Regarding Claim 1, Walt et al disclose an array composition comprising a rigid support; a molded layer; with at least a first assay location comprising discrete sites wherein said molded layer is adhered to said rigid support; a layer of bonding agent adhering said rigid support to said molded layer i.e. pattern of adhesive (Column 5, line 49-Column 6, line3 and lines 48-61); and a population of microspheres comprising at least a first and a second subpopulation wherein said first population comprises a first bioactive agent and said second population comprises a second bioactive agent wherein said microspheres are randomly distributed on said sites (Column 4, lines 35-66).

Regarding Claim 2, Walt et al disclose the array wherein said sites are separated by a distance of at least about 5μ m (Column 5, lines 12-17 and Claim 4).

Regarding Claim 3, Walt et al disclose the array wherein said sites are separated by a distance of at least about 100μ m (Column 5, lines 12-17 and Claim 4).

Regarding Claim 5, Walt et al disclose the array wherein said molded layer comprises at least a second assay location (Fig. 5 and 7).

Regarding Claim 6, Walt et al disclose the array wherein said assay locations are separated by a fluid barrier i.e. wells (Column 5, lines 61-66).

Regarding Claim 7, Walt et al disclose the array wherein said fluid barrier is a physical fluid barrier i.e. wells (Column 5, lines 61-66).

Regarding Claim 8, Walt et al disclose the array wherein said physical fluid barrier comprises a material that is added to said molded layer i.e. pattern of adhesive (Column 6, lines 52-61).

Regarding Claim 9, Walt et al disclose the array wherein said molded layer comprises said physical fluid barrier i.e. wells (Column 5, lines 61-66).

Regarding Claim 10, Walt et al disclose the array wherein said fluid barrier comprises a physico-chemical surface coating i.e. hydrophobic/hydrophilic functional grousp (Column 6, lines 64-66).

Regarding Claim 11, Walt et al disclose the array wherein the bioactive agents comprise nucleic acids (Column 9, lines 41-43).

Regarding Claim 12, Walt et al disclose the array wherein the bioactive agents comprise proteins (Column 8, lines 35-38).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 4 and 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (U.S. Patent No. 6,342,349 B1, filed 21 July 1998) and Walt et al (U.S. Patent No. 6,327,410 B1, filed 11 September 1998).

Regarding Claim 4, Walt et al teach an array composition comprising a rigid support; a molded layer; with at least a first assay location comprising discrete sites wherein said molded layer is adhered to said rigid support; a layer of bonding agent adhering said rigid support to said molded layer i.e. pattern of adhesive (Column 5, line 49-Column 6, line3 and lines 48-61); and a population of microspheres comprising at least a first and a second subpopulation wherein said first population comprises a first bioactive agent and said second population comprises a second bioactive agent wherein said microspheres are randomly distributed on said sites (Column 4, lines 35-66) and wherein the substrate is comprised of any one of numerous known substrate materials e.g. glass (Column 5, lines 31-47) and the size and shape of the substrate is variable depending on intended use (Column 4, lines 59-64) but they do not specifically teach the substrate is formatted to the dimensions of a microscope slide. However, substrates formatted to the dimensions of a microscope slide were well known in the art at the time the claimed invention was made as taught by Virtanen who teach a similar array composition comprising a rigid support, a molded layer adhered to the rigid support wherein the rigid support is formatted to the dimension of a microscope slide (Column 7, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the glass substrate of Walt et al and to format the glass substrate to the dimensions of a microscope slide as taught by Virtanen thereby providing a substrate which fits into detection apparatus designed for microscope slides. Based on available equipment, one skilled in the art would have been motivated to format the substrate

to the dimensions of a microscope slide for the obvious detecting bioactive agents on the substrate using available equipment.

Regarding Claim 15, Virtanen teaches a method of making an array comprising; contacting a surface of a template structure comprising projections (i.e. stamper) with a moldable material (i.e. disposable film); removing the template (stamp); adhering said molded layer to a rigid support (closing the valves thereby retaining the film on the substrate) (Column 62, lines 1-30 and Fig. 42) wherein the array composition comprises microspheres (Column 5, lines 61-66) and wherein the molded layer is a disposable film which reduces the amount of disposables (Column 62, lines 1-4) but Virtanen does not specifically teach randomly distributing microspheres on said molded layer. However, Walt et al teach a similar method of making an array comprising: providing a patterned surface having an adhesive layer (i.e. patterned adhesive, Column 6, lines 48-61) and further comprising randomly distributing microspheres on said layer such that individual discrete sites comprise microspheres wherein said microspheres comprise at least a first and second subpopulation and wherein said first and second subpopulation comprises a first bioactive agent and a second bioactive agent (Column 4, lines 35-66) wherein the random distribution of microspheres is faster and less expensive that the prior art techniques of spotting and *in situ* synthesis (Column 4, lines 53-56). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the random distribution of microspheres as taught by Walt et al to the assay plate of Virtanen thereby reducing costs and time of providing bioactive agents to the assay plate for the obvious benefits of economy of time and labor as taught by Walt et al (Column 4, lines 53-56). Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the molded layer of Virtanen to the array surface of Walt et al thereby providing renewable substrates (Column 7, lines 63-65) and reducing disposables as taught by Virtanen (Column 62, lines 1-4) for the expected benefits providing multiple (renewable) substrates while reducing costs of disposables and disposal.

Regarding Claim 16, Walt et al teach the method wherein said sites are separated by a distance of at least about 5μ m (Column 5, lines 12-17 and Claim 4).

Regarding Claim 17, Walt et al teach the method wherein said sites are separated by a distance of at least about 100μ m (Column 5, lines 12-17 and Claim 4).

Regarding Claim 18, Virtanen teaches the method wherein the template is cylindrical (Fig. 36, 38 or 39) and they teach the template is removed from the moldable material following stamping (Column 62, lines 23-30).

Regarding Claim 19, Virtanen teaches the method wherein the molded layer is flexible i.e. film made of elastic material (Column 62, lines 8-10).

Regarding Claim 20, Virtanen do not teach the molded layer is stored. However, they teach the molded layer is made of thin elastic material (Column 62, lines 8-10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to store the film of Virtanen in rolled form by rolling the thin film around a solid structure for the obvious benefits of safely and securely storing the thin film.

Regarding Claim 21, Virtanen teaches the method wherein said molded layer comprise at least a second assay location comprising discrete sites (Fig. 42) and Walt et al teach the method wherein said molded layer comprises at least a second assay location (Column 4, lines 59-66).

Regarding Claim 22, Virtanen teaches the method wherein the assay locations are separated by a fluid barrier i.e. wells (Column 62, lines 23-30) and Walt et al teach the method wherein said assay locations are separated by a fluid barrier i.e. wells (Column 5, lines 61-66).

Regarding Claim 23, Virtanen teaches the method further comprising adding a fluid barrier to said molded layer i.e. stamping to provide wells (Column 62, lines 23-30) and Walt et al teach the method further comprising adding a fluid barrier i.e. wells (Column 5, lines 61-66).

Regarding Claim 24, Virtanen teaches the method wherein the rigid support is formatted to the dimension of a microscope slide (Column 7, lines 57-59).

Regarding Claim 25, Virtanen teaches the method wherein the molded layer is used, disposed of and then replaced with another molded layer to provide a renewable surface (Column 7, lines 63-65) but Virtanen does not specifically teach applying a releasing agent to the surface of the template structure prior to contacting step. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply a releasing agent to the template based on the fact that the template is removed and reused for the obvious benefits of facilitating removal and reuse of the template.

Regarding Claim 26, Virtanen teaches the method wherein the molded layer is retained on the well plate during assays (Column 62, lines 27-30) but Virtanen does not specifically teach coating the coating the back of the molded layer with an adhering layer. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the molded layer of Virtanen by applying an adhering agent to the back of the layer thereby more securely maintaining the layer in the well plate. One skilled in the art would have been motivated to securely maintain the molded layer in the well plate to thereby an array composition which permits assays having rigorous method steps e.g. agitation and/or centrifugation.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
August 27, 2002